



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Vince Contreras, 240-669-2823; Vince.Contreras@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Broadly Neutralizing Antibodies against HIV-1 Directed to the CD4 Binding Site of HIV Envelope Protein

Description of Technology:

Inhibiting the ability of HIV-1, the virus that causes AIDS, to infect cells is one approach to both prevention and treatment of HIV. Scientists at the NIAID Vaccine Research Center have isolated and characterized neutralizing antibodies (VRC01, 02, 03, and 07) that bind to the CD4 binding site of HIV-1 envelope glycoprotein gp120. These human monoclonal antibodies can potentially be used as a therapeutic to: (1) treat an HIV infection, (2) decrease and prevent HIV-transmission from mother to infant, and (3) be effectively combined with anti-retroviral drug therapy. Additionally, the antibodies can be used for detection of HIV-1 infection in biological samples, including body fluids; and tissues from biopsies, autopsies, and pathology specimens.

VRC01 has been tested in several phase I clinical trials for safety and pharmacokinetics in infants, adults, and HIV-positive adults. VRC01 is currently being evaluated in a phase II clinical trial for prevention of HIV-1 acquisition.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Monoclonal antibodies to treat and/or diagnose HIV and/or AIDS
- Immunoassays and kits

Competitive Advantages:

- Monoclonal neutralizing antibodies prevent viral entry into cells
- Monoclonal neutralizing antibodies can be used for vaccine design and to develop diagnostics for HIV-1

Development Stage:

- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)
- Clinical Phase I

Inventors: John Mascola, Mark Connors, Peter Kwong, Gary Nabel, Mario Roederer, Xueling Wu (all from NIAID).

Publications:

Nabel G et al. (2015) Broadly Neutralizing Human Immunodeficiency Virus Type 1 Antibody Gene Transfer Protects Nonhuman Primates from Mucosal Simian-Human Immunodeficiency Virus Infection. *J Virol.* 89(16):8334-45. [PMID26041300].

Nabel G et al. (2014) Enhanced potency of a broadly neutralizing HIV-1 antibody in vitro improves protection against lentiviral infection in vivo. *J Virol.* 88(21):12669-82. [PMID:25142607].

Wu X et al. (2010) Immunotypes of a quaternary site of HIV-1 vulnerability and their recognition by antibodies. *J Virol.* 2011; 85(9):4578-85. [PMID:21325411].

Zhou T et al. (2010) Structural basis for broad and potent neutralization of HIV-1 by antibody VRC01. *Science.* 329(5993):811-7. [PMID: 20616231].

Intellectual Property: HHS Reference No: E-300-2009 and E-051-2012. The E-300-2009 family includes U.S. Patent Application. 13/498,286, filed March 23, 2012 (Issued); Australia Patent Application 2010298025, filed September 24, 2010 (Issued); China Patent Application 201080053616.5 filed September 24, 2010 (Issued); E.U. Patent Application 10760878.8 filed September 24, 2010 (Pending); India Patent Application 588/KOLNP/2012 filed March 13, 2012 (Pending); South Africa Patent Application 212/02116 filed September 24, 2017 (Pending); Canada Patent Application. 2274636 filed September 24, 2017 (Pending).

The E-051-2012 family includes U.S. Patent Application 14-363,740, filed June 6, 2014 (Issued); Australia Patent Application. 2012347453, filed December 10, 2010 (Issued); China Patent Application 201280069415.3, filed December 10, 2012 (Pending); E.U. Patent Application 1285597.6, filed December 10, 2012 (Pending); Indian Patent Application 4661/DELNP/2014, filed December 10, 2012 (Pending); South Africa Patent Application 2014/04077, filed December 10, 2012 (Pending).

Licensing Contact: Dr. Vince Contreras, 240-669-2823; Vince.Contreras@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Monoclonal antibodies to treat and/or diagnose HIV and/or AIDS.

For collaboration opportunities, please contact Dr. Vince Contreras, 240-669-2823;

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Suzanne Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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